K130082

II. 510(k) Summary

DEC 20 2013

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3. DATE PREPARED: December 16, 2013

4. DEVICE INFORMATION

DEVICE NAME: GenPrime Drugs of Abuse Reader System

Common Name: Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use

Classification Panel: Clinical Toxicology (91) and Clinical Chemistry (75)

Classification Names: Regulatory information applicable to the test system is provided below:

CFR Section	Product Code
Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use	JQT
862.3100, Amphetamine Test System	DKZ
862.3150, Barbiturate Test System	DIS
862.3250, Cocaine and cocaine metabolite Test System	DIO
862.3620, Methadone Test System	DJR
862.3610, Methamphetamine Test System	DJC
862.3640, Morphine Test System	DNK
862.3650, Opiate Test System	DJG
Unclassified, Phencyclidine Test System	LCM
862.3870, Cannabinoid Test System	LDJ

DEVICE CLASSIFICATION: Class II

5. PREDICATE DEVICE: PROFILE®-V MEDTOXScan® Drugs of Abuse Test System,(K080635)

6. DEVICE DESCRIPTION:

The GenPrime Drugs of Abuse (DOA) Reader System consists of a small, portable high resolution flat bed scanner, customized GenPrime DOA Reader Software, and lateral flow tests that are intended for use in the system. The scanner has a custom Scanner Lid with an opening for the test device, and a Scanner Stand, which places the scanner bed at the appropriate angle for running and reading the test devices. The System is currently intended for use with two test devices, the OS Cup and the Split Key Cup, both of which are rapid, single use, disposable immunochromatographic tests for the qualitative detection of drugs of abuse in human urine.

An image of a compatible test device is captured and the software algorithm determines from the image whether the presence or absence of colored test lines is associated with a positive or negative result for each analyte on a test format. The software also confirms the validity of the results by verifying the presence of control lines. The results are recorded and logged into a database along with an image of the test, patient and operator information and the time of image capture. The results can be viewed, printed, or sent to a recipient via email or other electronic method. The GenPrime DOA Reader is for *in vitro* diagnostic use and is intended for use in laboratories, point-of-care sites and workplaces by minimally trained users. The test is not intended for over-the-counter use.

OS Cup device

The GenPrime DOA Reader System detects drug classes at the following cutoff concentrations for the OS Cup device:

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
BAR	Barbiturates (Secobarbital)	300 ng/mL
COC	Cocaine (Benzoylecgonine)	150 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

Configurations of the OS Cup may consist of any combination of the above listed drug analytes. Refer to specific product labeling for the combination of drug tests included in that test device.

Split Key Cup device

The GenPrime DOA Reader System detects drug classes at the following cutoff concentrations for the Split Key Cup device:

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
MTD	Methadone (Methadone)	300 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
MOP 300	Morphine	300 ng/mL
MOP 2000	Morphine	2000 ng/mL
OXY	Oxycodone (Oxycodone)	100 ng/mL
PCP	Phencyclidine (Phencyclidine)	25 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

Configurations of the Split Key Cup may consist of any combination of the above listed drug analytes. Refer to specific product labeling for the combination of drug tests included in that test device.

7. INDICATIONS FOR USE:

The GenPrime Drugs of Abuse (DOA) Reader System consists of the GenPrime DOA Reader, GenPrime DOA Windows®-compatible Software and compatible qualitative immunochromatographic, OS Cup and Split Key Cup (SK Cup), test devices. The GenPrime DOA Reader System is for *in vitro* diagnostic use and is intended for prescription use in laboratories, point-of-care and workplaces by trained users. The test is not intended for over-the-counter use. The GenPrime DOA Reader System test devices cannot be read visually. The GenPrime DOA Reader and compatible DOA test devices qualitatively detect drug classes in human urine at the cutoff concentrations shown below:

OS Cup

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
BAR	Barbiturates (Secobarbital)	300 ng/mL
COC	Cocaine (Benzoylecgonine)	150 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

SK Cup

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
MTD	Methadone	300 ng/mL
MOP 300	Morphine	300 ng/mL
MOP 2000	Morphine	2000 ng/mL
OXY	Oxycodone (Oxycodone)	100 ng/mL
PCP	Phencyclidine (Phencyclidine)	25 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

Configurations of the OS Cup and SK Cup may consist of any combination of the above listed drug analytes associated with the respective cup.

The GenPrime DOA reader system provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The GenPrime DOA Reader compatible test devices are identified using barcodes and/or label(s) on the panel housing. The GenPrime DOA Reader and Software use characteristics from this labeling to measure the quality of each image as it is generated. This ensures that each test result obtained and interpreted by the System has been first checked for its quality.

Special conditions for use statement(s):
The device is for *in vitro* diagnostic prescription use.

The GenPrime DOA Reader System test devices cannot be read visually.

The GenPrime DOA Reader System only provides a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The test is not intended for over-the-counter use.

Special instrument requirements:

- The GenPrime DOA Reader is required.
- The GenPrime DOA Reader Software must be loaded onto a PC, laptop computer or Windows compatible device meeting the following minimum requirements:

GenPrime DOA Reader Software System Requirements
Operating System
MS Windows® XP with Service Pack 3, MS Windows® Vista, or MS Windows® 7
PC
Minimum Processor: Intel® Pentium® 4 1.5 GHz or equivalent
Minimum RAM: 1 GB
Free hard disc space: minimum of 50 MB at Installation, needs additional disc space while operating; an additional 850 MB necessary for installation of MS .NET Framework 4.0
Mouse for optimal interaction with user interface (e.g. IntelliMouse® / Microsoft®)
Standard keyboard with cursor keys, Num-Pad and Insert-, Delete-, Page up/down keys. Recommended with cable.
Minimum: 1 USB 2.0-compatible port
External Software
PDF-Compatible viewing application, i.e. Adobe Reader

8. DISCUSSION OF TECHNOLOGICAL CHARACTERISTICS:

a. **Similarities and differences to predicate device**

Both the applicant and the predicate test systems are used to detect the presence of drugs of abuse and their metabolites in human urine. In both systems, a urine sample is added to the test device and allowed to react for a specified period of time, after which an instrument is used to read the test device and interpret and display the test result. Both the applicant and predicate test device are rapid single use disposable devices that use established immunochromatographic lateral flow technology. Both the applicant and predicate test utilize gold-conjugated reagents to generate reddish-purple test and control lines, which are read by the instrument. Both devices are competitive assays where concentration of drug is inversely related to the signal detected by the instrument. The applicant device measures line intensities using image analysis algorithms and then performs the analysis and outputs the results via a Windows compatible computer. The predicate device uses a CIS (contact imaging sensor) to measure line intensity and performs the analysis and outputs results using an embedded operating system and display. The applicant device requires that the operator manually time test development (5 minutes) and then operate the instrument, while the predicate instrument internally times test strip development (10 minutes) and then scans the test cassette. The overall performance and characteristics of the GenPrime DOA Reader System and the predicate device, the MEDTOXScan® are summarized in Table 1 below:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Determines qualitative positive or negative result from drugs of abuse immunoassay screens	Determines qualitative positive or negative result from drugs of abuse immunoassay screens
Single-Use Test Device	Produces colored lines on device.	Same
Assay Type	Competitive assay where concentration of drug is inversely related to the visible signal detected by the instrument.	Same
System Procedure	Sample is added to a single use test device, which is then read by instrument. Instrument is designed to read multiple single use test devices, one at a time.	Same
Measurement Method	Scans the single-use test device to detect a signal.	Same
Differences		
Item	**Device**	**Predicate**
Test Device Format	Reads multiple formats of single-use test devices in different cup formats.	Reads a single-use test cassette.
Test Time and Timing Method	Operator manually times test development for 5 minutes and then operates the instrument.	Instrument internally times test strip development for 10 minutes and then scans the test cassette.
Detection Method	Measures density of visible lines against background on single-use test device.	Measures reflectance of visible lines on single use test cassette.
Output	Outputs "presumptive positive", "negative", and "invalid" test results on a graphic user interface displayed on a computer screen and automatically stores results along with test information. Operator has ability to print and/or export results.	Outputs "positive," "negative," and "invalid" test results on paper printout or LCD screen; stores and uploads results.
Cutoff values	BAR cutoff is 300ng MTD cutoff is 300ng	BAR cutoff is 200ng MTD cutoff is 200ng
Power Requirements	AC power only	AC or battery power
Additional Requirements	Windows®-based computer and cable accessories	None.

Table 1. Comparison of Similarities and Difference for the GenPrime DOA Reader System and predicate system.

GenPrime believes that the technological characteristics of the GenPrime DOA Reader System are substantially similar to those of the predicate device.

9. DISCUSSION OF NON-CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

Laboratory performance studies were conducted to determine the substantial equivalence of the GenPrime Drugs of Abuse Reader System to the predicate system. These studies are as follows:

Sensitivity/Precision/Distribution of Random Error

The precision studies were performed in the hands of the intended users at at three sites representative of laboratory, workplace, and POC settings. The studies were performed with a minimum of two skilled intended use operators per site. The operators performed the tests following the instructions for use, which are included with the GenPrime DOA Reader and with each test device intended for use with the GenPrime DOA Reader System.

The clinical protocols and details for the POC sites and the operators where the studies were conducted are provided in Section XVII, Performance Testing, Clinical, below.

Precision studies were performed with the target analytes at 0%, 25%, 50%, 75%, 125%, 150%, 175%, and 200% of the cutoff during a 20 working day period. The identity of the samples was masked from the operator. Each urine specimen was labeled with a unique alpha-numeric sample ID prior to delivery to the POC sites.

Performance of the GenPrime DOA Reader was evaluated for each drug analyte by testing each drug at the stated concentration using a minimum of 10 tests per operator. Each of the operators used a different GenPrime DOA Reader. Results for this study are summarized in Tables 2a and 2b below:

Table 2a. Sensitivity/Precision/Distribution of Random Error for the OS Cup

OS Cup, AMP (500 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	100	57	57	0	100%
50%	250	57	57	0	100%
75%	375	57	19	38	33.3%
125%	625	58	2	56	96.6%
150%	750	58	0	58	100%
175%	875	57	0	57	100%
200%	1000	57	0	57	100%
OS Cup, BAR (300 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	75	57	57	0	100%
50%	150	57	57	0	100%
75%	225	57	22	35	38.6%
125%	375	58	3	55	94.8%
150%	450	58	0	58	100%
175%	525	57	0	57	100%
200%	600	57	0	57	100%
OS Cup, COC (150 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	37.5	57	57	0	100%
50%	75	57	57	0	100%
75%	112.5	57	14	43	24.6%
125%	187.5	58	1	57	98.3%
150%	225	58	0	58	100%
175%	262.5	57	0	57	100%
200%	300	57	0	57	100%
OS Cup, MET (500 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	100	57	57	0	100%
50%	250	57	57	0	100%
75%	375	57	18	39	31.6%
125%	625	58	0	58	100%
150%	750	58	0	58	100%
175%	875	57	0	57	100%
200%	1000	57	0	57	100%

Table 2a. Sensitivity/Precision/Distribution of Random Error for the OS Cup, continued

OS Cup, THC (50 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	65	65	0	100%
25%	12.5	57	57	0	100%
50%	25	57	57	0	100%
75%	37	57	46	11	80.7%
125%	62	58	7	51	87.9%
150%	75	58	0	58	100%
175%	87.5	57	0	57	100%
200%	100	57	0	57	100%

Table 2b. Sensitivity/Precision/Distribution of Random Error for the SK Cup

SK Cup, AMP (500 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	100	88	88	0	100%
50%	250	84	84	0	100%
75%	375	85	47	38	55.3%
125%	625	84	3	81	96.4%
150%	750	85	0	85	100%
175%	875	87	0	87	100%
200%	1000	89	0	89	100%
SK Cup, MET (500 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	100	88	88	0	100%
50%	250	84	84	0	100%
75%	375	85	57	28	67.1%
125%	625	84	4	80	95.2%
150%	750	85	0	85	100%
175%	875	87	0	87	100%
200%	1000	89	0	89	100%
SK Cup, MTD (300 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	75	88	88	0	100%
50%	150	84	84	0	100%
75%	225	85	72	13	84.7%
125%	375	84	10	74	88.1%
150%	450	85	0	85	100%
175%	525	87	0	87	100%
200%	600	89	0	89	100%
SK Cup, MOP (300 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	75	45	45	0	100%
50%	150	45	43	2	96%
75%	225	46	29	17	63.0%
125%	375	45	4	41	91.1%
150%	450	45	1	44	98%
175%	525	45	0	45	100%
200%	600	46	0	46	100%

Table 2b. Sensitivity/Precision/Distribution of Random Error for the SK Cup, continued

SK Cup, MOP (2000 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	500	88	88	0	100%
50%	1000	84	84	0	100%
75%	1500	85	63	22	74.1%
125%	2500	84	11	73	86.9%
150%	3000	85	0	85	100%
175%	3500	87	0	87	100%
200%	4000	89	0	89	100%
SK Cup, OXY (100 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	25	88	88	0	100%
50%	50	84	84	0	100%
75%	75	85	57	28	67.1%
125%	125	84	15	69	82.1%
150%	150	85	0	85	100%
175%	175	87	0	87	100%
200%	200	89	0	89	100%
SK Cup, PCP (25 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	6.25	88	88	0	100%
50%	12.5	84	84	0	100%
75%	18.75	85	50	35	58.8%
125%	31.25	84	6	78	92.9%
150%	37.5	85	0	85	100%
175%	43.75	87	0	87	100%
200%	50	89	0	89	100%
SK Cup, THC (50 ng/mL)					
% of Cutoff	ng/mL	N	# NEG	# POS	Precision
NEG	0	86	86	0	100%
25%	12.5	88	88	0	100%
50%	25	84	84	0	100%
75%	37	85	63	22	74.1%
125%	62	84	14	70	83.3%
150%	75	85	0	85	100%
175%	87.5	87	0	87	100%
200%	100	89	0	89	100%

Related Compounds and Cross Reactants

Analytical specificity studies were performed to determine whether drugs and drug metabolites within the same class of drugs or with similar molecular structures cross-react in the test system. Results are expressed as the minimum concentration required to produce a positive result in the indicated assay.

Reference standards for the various metabolites and compounds were prepared at 100 µg/mL in pooled negative human urine samples. Compounds that tested positive were serially diluted until a negative result was observed. Results shown are expressed as the minimum concentration producing a positive result in the indicated assay. A list of these compounds and their level of cross reactivity is shown for the OS Cup in Table 3 below and for the Split Key Cup in Table 4 below.

Table 3. OS Cup Related Compounds and Cross-Reactants

Related Compound or Cross-Reactant	Result	% Cross Reactive
Amphetamines (AMP)(d-Amphetamine) 500 ng/mL		
3,4-Methylendioxyamphetamine (MDA)	Positive at 500 ng/mL	100%
Amphetamine (d,l)	Positive at 1000 ng/mL	50%
Phentermine	Positive at 2250 ng/mL	22%
b-Phenylethylamine (phenethylamine)	Positive at 50000 ng/mL	1%
3,4-methylenedioxy-N-ethylamphetamine-MDEA	Negative at 100000 ng/mL	N/A
Amphetamine (l)	Negative at 100000 ng/mL	N/A
(1R,2S)-(-)-Ephedrine	Negative at 100000 ng/mL	N/A
3,4-Methylenedioxymethamphetamine (MDMA)	Negative at 100000 ng/mL	N/A
Fenfluramine	Negative at 100000 ng/mL	N/A
Methamphetamine (d)	Negative at 100000 ng/mL	N/A
Methamphetamine (l)	Negative at 100000 ng/mL	N/A
Tryptamine	Negative at 100000 ng/mL	N/A
Tyramine	Negative at 100000 ng/mL	N/A
Barbiturate (BAR) (Secobarbital) (300 ng/mL)		
Butabarbital	Positive at 75 ng/mL	400%
Butethal	Positive at 250 ng/mL	120%
Pentobarbital	Positive at 250 ng/mL	120%
Phenobarbital	Positive at 250 ng/mL	120%
Aprobarbital	Positive at 400 ng/mL	75%
Barbital	Positive at 500 ng/mL	60%
Alphenal	Positive at 600 ng/mL	50%
Amobarbital	Positive at 850 ng/mL	35%
Cyclopentobarbital	Positive at 1500 ng/mL	20%
Allobarbital	Positive at 3500 ng/mL	9%
Butalbital	Positive at 11000 ng/mL	3%
Mephobarbital	Positive at 100000 ng/mL	0%
Barbituric Acid	Negative at 100000 ng/mL	N/A
Glutethimide	Negative at 100000 ng/mL	N/A
Hexobarbital	Negative at 100000 ng/mL	N/A
Phenytoin (diphenylhydantoin)	Negative at 100000 ng/mL	N/A
Thiopental	Negative at 100000 ng/mL	N/A
Cocaine (COC) (Benzoylecgonine) 150 ng/mL		
Cocaethylene	Positive at 4000 ng/mL	4%
Cocaine	Positive at 10000 ng/mL	2%
Ecgonine	Positive at 10000 ng/mL	2%
Ecgonine Methyl Ester	Negative at 100000 ng/mL	N/A
Methamphetamines (MET) (d-Methamphetamine) 500 ng/mL		
3,4-Methylenedioxymethamphetamine (MDMA)	Positive at 1250 ng/mL	40%
Methamphetamine (l)	Positive at 6000 ng/mL	8%
3,4-methylenedioxy-N-ethylamphetamine-MDEA	Positive at 25000 ng/mL	2%
b-Phenylethylamine (phenethylamine)	Positive at 25000 ng/mL	2%
p-Hydroxymethamphetamine	Positive at 25000 ng/mL	2%
Amphetamine (d)	Positive at 50000 ng/mL	1%
Chloroquine	Positive at 50000 ng/mL	1%
Mephentermine	Positive at 50000 ng/mL	1%
3,4-Methylendioxyamphetamine (MDA)	Negative at 100000 ng/mL	N/A
Amphetamine (d,l)	Negative at 100000 ng/mL	N/A
Amphetamine (l)	Negative at 100000 ng/mL	N/A
Ephedrine	Negative at 100000 ng/mL	N/A
Fenfluramine	Negative at 100000 ng/mL	N/A
Phenmetrazine	Negative at 100000 ng/mL	N/A
Phentermine	Negative at 100000 ng/mL	N/A
Phenylephrine (l)	Negative at 100000 ng/mL	N/A
Procaine	Negative at 100000 ng/mL	N/A
Tyramine	Negative at 100000 ng/mL	N/A

Table 3. OS Cup Related Compounds and Cross-Reactants, continued

Related Compound or Cross-Reactant	Result	% Cross Reactive
Marijuana (THC) (11-nor-D9-THC-9 COOH) 50 ng/mL		
11-nor-D8-THC-9 COOH	Positive at 50 ng/mL	100%
11-Hydroxy- Δ9-THC	Positive at 5000 ng/mL	1%
Cannabinol	Positive at 20000 ng/mL	0%
Δ9-THC	Negative at 100000 ng/mL	N/A
Cannabidiol	Negative at 100000 ng/mL	N/A
Δ8-THC	Negative at 100000 ng/mL	N/A

Table 4. Split Key Cup Related Compounds and Cross-Reactants

Related Compound or Cross-Reactant	Result	% Cross Reactive
Amphetamines (AMP) (d-Amphetamine) 500 ng/mL		
Amphetamine (d,l)	Positive at 1000 ng/mL	50%
3,4-Methylendioxyamphetamine (MDA)	Positive at 4000 ng/mL	13%
b-Phenylethylamine (phenethylamine)	Positive at 25000 ng/mL	2%
3,4-methylenedioxy-N-ethylamphetamine-MDEA	Negative at 100000 ng/mL	1%
(1R,2S)-(-)-Ephedrine	Negative at 100000 ng/mL	N/A
3,4-Methylenedioxymethamphetamine (MDMA)	Negative at 100000 ng/mL	N/A
Amphetamine (l)	Negative at 100000 ng/mL	N/A
Fenfluramine	Negative at 100000 ng/mL	N/A
Methamphetamine (d)	Negative at 100000 ng/mL	N/A
Methamphetamine (l)	Negative at 100000 ng/mL	N/A
Phentermine	Negative at 100000 ng/mL	N/A
Tryptamine	Negative at 100000 ng/mL	N/A
Tyramine	Negative at 100000 ng/mL	N/A
Methamphetamines (MET) (d-Methamphetamine) 500 ng/mL		
3,4-Methylenedioxymethamphetamine (MDMA)	Positive at 1000 ng/mL	50%
Methamphetamine (l)	Positive at 5000 ng/mL	10%
p-Hydroxymethamphetamine	Positive at 15000 ng/mL	3%
b-Phenylethylamine (phenethylamine)	Positive at 50000 ng/mL	1%
Chloroquine	Positive at 50000 ng/mL	1%
Mephentermine	Positive at 50000 ng/mL	1%
3,4-Methylendioxyamphetamine (MDA)	Negative at 100000 ng/mL	N/A
3,4-methylenedioxy-N-ethylamphetamine-MDEA	Negative at 100000 ng/mL	N/A
Amphetamine (d,l)	Negative at 100000 ng/mL	N/A
Amphetamine (d)	Negative at 100000 ng/mL	N/A
Amphetamine (l)	Negative at 100000 ng/mL	N/A
Ephedrine	Negative at 100000 ng/mL	N/A
Fenfluramine	Negative at 100000 ng/mL	N/A
Methamphetamines (MET) (d-Methamphetamine) 500 ng/mL, continued		
Phenmetrazine	Negative at 100000 ng/mL	N/A
Phentermine	Negative at 100000 ng/mL	N/A
Phenylephrine (l)	Negative at 100000 ng/mL	N/A
Procaine	Negative at 100000 ng/mL	N/A
Tyramine	Negative at 100000 ng/mL	N/A

Table 4. Split Key Cup Related Compounds and Cross-Reactants, continued

Related Compound or Cross-Reactant	Result	% Cross Reactive
Morphine (MOP) (Morphine) 300 ng/mL		
Morphine 6-β-D-Glucuronide	Positive at 250 ng/mL	120%
6-Monoacetylmorphine (6-MAM)	Positive at 300 ng/mL	100%
Codeine	Positive at 300 ng/mL	100%
Diacetylmorphine	Positive at 500 ng/mL	60%
Dihydrocodeine	Positive at 2500 ng/mL	12%
Morphine 3-β-D-Glucuronide	Positive at 3000 ng/mL	10%
Ethylmorphine	Positive at 5000 ng/mL	6%
Hydromorphone	Positive at 10000 ng/mL	3%
Thebaine	Positive at 20000 ng/mL	2%
Hydrocodone	Positive at 25000 ng/mL	1%
Nalorphine	Positive at 50000 ng/mL	1%
Apomorphine	Negative at 100000 ng/mL	N/A
Levorphanol (tartrate dihydrate)	Negative at 100000 ng/mL	0%
Naloxone	Negative at 100000 ng/mL	N/A
Naltrexone	Negative at 100000 ng/mL	N/A
Norcodeine	Negative at 100000 ng/mL	N/A
Norhydrocodone	Negative at 100000 ng/mL	N/A
Normorphine	Negative at 100000 ng/mL	N/A
Noroxymorphone	Negative at 100000 ng/mL	N/A
Oxycodone	Negative at 100000 ng/mL	N/A
Oxymorphone	Negative at 100000 ng/mL	N/A
Procaine	Negative at 100000 ng/mL	N/A
Methadone (MTD) (Methadone) 300 ng/mL		
Buprenorphine (MTD Replacement)	Negative at 100000 ng/mL	N/A
EDDP (Primary Metabolite)	Negative at 100000 ng/mL	N/A
EMDP (Secondary Metabolite)	Negative at 100000 ng/mL	N/A
Morphine (MOP) (Morphine) 2000 ng/mL		
Morphine 6-β-D-Glucuronide	Positive at 2500 ng/mL	80%
Nalorphine	Positive at 2500 ng/mL	80%
Codeine	Positive at 3000 ng/mL	67%
Hydromorphone	Positive at 4000 ng/mL	50%
6-Monoacetylmorphine (6-MAM)	Positive at 5000 ng/mL	40%
Dihydrocodeine	Positive at 5000 ng/mL	40%
Ethylmorphine	Positive at 5000 ng/mL	40%
Morphine 3-β-D-Glucuronide	Positive at 5000 ng/mL	40%
Normorphine	Positive at 10000 ng/mL	20%
Hydrocodone	Positive at 12500 ng/mL	16%
Diacetylmorphine	Positive at 15000 ng/mL	13%
Norcodeine	Positive at 15625 ng/mL	13%
Oxymorphone	Positive at 25000 ng/mL	8%
Thebaine	Positive at 25000 ng/mL	8%
Apomorphine	Negative at 100000 ng/mL	N/A
Levorphanol (tartrate dihydrate)	Negative at 100000 ng/mL	N/A
Naloxone	Negative at 100000 ng/mL	N/A
Naltrexone	Negative at 100000 ng/mL	N/A
Norhydrocodone	Negative at 100000 ng/mL	N/A
Noroxymorphone	Negative at 100000 ng/mL	N/A
Oxycodone	Negative at 100000 ng/mL	N/A
Procaine	Negative at 100000 ng/mL	N/A

Table 4. Split Key Cup Related Compounds and Cross-Reactants, continued

Related Compound or Cross-Reactant	Result	% Cross Reactive
Oxycodone (OXY) (Oxycodone) 100 ng/mL		
Oxymorphone	Positive at 400 ng/mL	25%
Noroxymorphone	Positive at 2500 ng/mL	4%
Hydrocodone	Positive at 12500 ng/mL	1%
Naloxone	Positive at 37500 ng/mL	0%
Hydromorphone	Positive at 50000 ng/mL	0%
Levorphanol	Positive at 50000 ng/mL	0%
Naltrexone	Positive at 50000 ng/mL	0%
Norhydrocodone	Positive at 50000 ng/mL	0%
6-Monoacetylmorphine	Negative at 100000 ng/mL	N/A
Apomorphine	Negative at 100000 ng/mL	N/A
Codeine	Negative at 100000 ng/mL	N/A
Diacetylmorphine	Negative at 100000 ng/mL	N/A
Dihydrocodeine	Negative at 100000 ng/mL	N/A
Ethylmorphine	Negative at 100000 ng/mL	N/A
Morphine	Negative at 100000 ng/mL	N/A
Morphine 3-β-D-Glucuronide	Negative at 100000 ng/mL	N/A
Morphine 6-β-D-Glucuronide	Negative at 100000 ng/mL	N/A
Nalorphine	Negative at 100000 ng/mL	N/A
Norcodeine	Negative at 100000 ng/mL	N/A
Normorphine	Negative at 100000 ng/mL	N/A
Thebaine	Negative at 100000 ng/mL	N/A
Phencyclidine (PCP) (Phencyclidine) 25 ng/mL		
4-Hydroxyphencyclidine	Positive at 1500 ng/mL	2%
Marijuana (THC) (11-Nor-9-carboxy-Δ9-THC) 50 ng/mL		
11-Hydroxy- Δ9-THC	Positive at 5000 ng/mL	1%
11-nor-D8-THC-9 COOH	Positive at 5000 ng/mL	1%
Cannabinol	Positive at 20000 ng/mL	0%
Cannabidiol	Negative at 100000 ng/mL	N/A
Δ8-THC	Negative at 100000 ng/mL	N/A
Δ9-THC	Negative at 100000 ng/mL	N/A

Interference Data

pH and Specific Gravity

The GenPrime DOA Reader System was assayed with pH values of 3.0, 4.0, 7.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with drug concentrations at 50% (negative) and 150% (positive) of cutoff. For both the OS and SK Cups, all four pH samples gave negative results in the 50% of cutoff level for each drug, and all gave positive results at the 150% of cutoff level for each drug.

The GenPrime DOA Reader System was assayed in triplicate with samples with specific gravity values of 1.003, 1.015 and 1.030 ± 0.001. The specific gravity samples were fortified with drug concentrations as described above for pH to give strong negative and strong positive results. All three specific gravity samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

Common Drugs

Drug free urine samples were spiked with drug concentrations that were at 50% (negative) and 150% (positive) of cutoff. Concentrations of 100,000 ng/mL of the common drugs were then added to the preparation and assayed by the GenPrime DOA Reader System. If a common compound name is followed by the drug abbreviation (e.g., "BAR"), then it has expected reactivity in the specified drug test (see Related Compounds and Cross Reactants) and was not assayed for interference in that drug test. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results for the OS Cup (Table 5) or the Split Key Cup (Table 6).

Table 5. Common Drugs Evaluated with the OS Cup with the GenPrime DOA Reader System.

Acetylsalicylic Acid	Chlorpheniramine	Phenobarbital - **BAR**
Acetaminophen	Cocaine - **COC**	Phenytoin (Diphenylhydantoin) - **BAR**
Brompheniramine maleate	Dextromethorphan	d-Pseudoephedrine
Caffeine	Doxylamine	Salicylic Acid
Carbamazepine	Ibuprofen	

Table 6. Common Drugs Evaluated with the Split Key Cup with the GenPrime DOA Reader System.

Acetylsalicylic Acid	Chlorpheniramine	Ibuprofen
Acetaminophen	Cocaine	Morphine - **MOP**
Brompheniramine maleate	Dextromethorphan	d-Pseudoephedrine
Caffeine	Doxylamine	Salicylic Acid
Carbamazepine		

Discussion of Clinical Tests Performed for Determination of Substantial Equivalence

The accuracy of the GenPrime DOA Reader System was evaluated at three POC sites with blind coded clinical urine samples that contained varying concentrations of drugs as determined by GC/MS or LC/MS/MS. For each drug, a minimum of 40 unaltered positive and 40 unaltered negative clinical samples were assessed. Negative samples were screened negative by EIA, 10% of which were also confirmed by GC/MS or LC/MS/MS. No false positive results were found for the negative samples (0% of cutoff). Results were stratified to give values of 0%, 0% - 50%, 50% - 100%, 100% - 150% and > 150% of cutoff. At least 10% of the samples were in the near cutoff ranges of 50% - 100% and 100% - 150%. Results summaries are provided below in Table 7 for the OS Cup and Table 8 for the Split Key Cup, for all sites combined.

Discordant results and the drug levels detected by GC/MS or LC/MS/MS are provided in Table 9 for the OS Cup and Table 10 for the Split Key Cup.

Table 7. Summary of method comparison data for the OS Cup (all sites combined)

DRUG (cutoff)	GenPrime Test System OS Cup	No Drug	Negative (Less than -50% of cutoff)	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (Between cutoff and +50%)	Positive (greater than +50% of cutoff)	GenPrime OS Cup Agreement with Reference
AMP (500)	Positive	0	0	3	5	36	100%
	Negative	40	1	4	0	0	94%
BAR (300)	Positive	0	0	3	4	36	100%
	Negative	40	11	1	0	0	95%
COC (150)	Positive	0	0	3	4	38	100%
	Negative	40	0	1	0	0	93%
MET (500)	Positive	0	0	2	4	36	100%
	Negative	40	8	2	0	0	96%
THC (50)	Positive	0	0	0	4	36	100%
	Negative	40	0	4	0	0	100%
All Drugs	Positive	0	0	12	25	222	100%
	Negative	240	20	15	0	0	95.8%

Table 8. Summary of method comparison data for the Split Key Cup (all sites combined)

DRUG (cutoff)	GenPrime Test System SK Cup	No Drug	Negative (Less than -50% of cutoff)	Near Cutoff Negative (between -50% and cutoff)	Near Cutoff Positive (Between cutoff and +50%)	Positive (greater than +50%)	GenPrime SK Cup Agreement with Reference
AMP (500)	Positive	0	0	4	4	36	100%
	Negative	40	1	4	0	0	92%
MET (500)	Positive	0	0	1	4	36	100%
	Negative	40	0	3	0	0	98%
MOP (300)	Positive	0	0	1	3	36	98%
	Negative	40	0	3	1	0	98%
MTD (300)	Positive	0	0	0	4	36	100%
	Negative	40	0	4	0	0	100%
MOP (2000)	Positive	0	0	2	4	37	100%
	Negative	40	1	3	0	0	96%
OXY (150)	Positive	0	0	2	4	36	100%
	Negative	40	0	2	0	0	95%
PCP (25)	Positive	0	0	0	4	39	100.0%
	Negative	40	0	4	0	0	100.0%
THC (50)	Positive	0	0	0	3	38	97.6%
	Negative	40	33	7	1	0	100.0%
All Drugs	Positive	0	0	13	34	332	99.5%
	Negative	360	51	31	2	0	97.1%

Table 9. Discordant Results for the OS Cup

Cutoff Value (ng/mL)	Drug	GenPrime DOA Reader System	GC/MS or LC/MS/MS Value
500	AMP	Presumptive Positive	Amphetamine at 306 ng/mL
	AMP	Presumptive Positive	Amphetamine at 437 ng/mL
	AMP	Presumptive Positive	Amphetamine at 370 ng/mL
300	BAR	Presumptive Positive	Phenobarbital at 210 ng/mL (=252 ng/mL BAR equiv)
	BAR	Presumptive Positive	Butalbital at 6000 ng/mL (=240 ng/mL BAR equiv)
	BAR	Presumptive Positive	Butalbital at 4644 ng/mL (=186 ng/mL BAR equiv)
150	COC	Presumptive Positive	Benzoylecgonine at 130 ng/mL
	COC	Presumptive Positive	Benzoylecgonine at 110 ng/mL
	COC	Presumptive Positive	Benzoylecgonine at 126 ng/mL
500	MET	Presumptive Positive	Methamphetamine at 264 ng/mL
	MET	Presumptive Positive	Methamphetamine at 277 ng/mL

Table 10. Discordant Results for the Split Key Cup

Cutoff Value (ng/mL)	Drug	GenPrime DOA Reader System	GC/MS or LC/MS/MS Value
500	AMP	Presumptive Positive	Amphetamine at 250 ng/Ml
	AMP	Presumptive Positive	Amphetamine at 437 ng/mL
	AMP	Presumptive Positive	Amphetamine at 365 ng/mL
	AMP	Presumptive Positive	Amphetamine at 370 ng/mL
500	MET	Presumptive Positive	Amphetamine at 307 ng/mL
300	MOP	Negative	Codeine at 333 ng/mL (=333 ng/mL MOP equiv)
	MOP	Presumptive Positive	Codeine at 283 ng/mL (=283 ng/mL MOP equiv)

Table 10. Discordant Results for the Split Key Cup, continued

Cutoff Value (ng/mL)	Drug	GenPrime DOA Reader System	GC/MS or LC/MS/MS Value
2000	MOP	Presumptive Positive	Morphine at 377 ng/mL, Codeine at 2097 ng/mL (=1782 MOP equiv)
	MOP	Presumptive Positive	Morphine at 962 ng/mL, Codeine at 1437 ng/mL (=1925 MOP equiv)
100	OXY	Presumptive Positive	Oxycodone at 65 ng/mL
	OXY	Presumptive Positive	Oxycodone at 50 ng/mL
50	THC	Negative	11-nor-9-carboxy-D9-THC at 59 ng/mL

Conclusion

The GenPrime DOA Reader System has the same intended use, similar technological characteristics and equivalent precision, interference, cross-reactivity and clinical accuracy as the predicate device. The data demonstrate that any differences in technological characteristics do not raise any new issues of safety or effectiveness. GenPrime believes that the GenPrime DOA Reader System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

GENPRIME, INC
C/O MAUREEN GARNER, PRESIDENT
NEW WORLD REGULATORY SOLUTIONS
1983 HAZELWOOD ROAD
TOMS RIVER NJ 08753

Re: K130082
Trade/Device Name: GenPrime Drugs of Abuse Reader System
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DIS, DIO, LDJ, DJR, DJC, DJG, LCM, DNK, JQT
Dated: December 06, 2013
Received: December 09, 2013

Dear Ms. Garner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130082

Device Name: GenPrime Drugs of Abuse Reader System

Indications for Use:
The GenPrime Drugs of Abuse (DOA) Reader System consists of the GenPrime DOA Reader, GenPrime DOA Windows®-compatible software and compatible qualitative immunochromatographic, OS Cup and Split Key Cup (SK Cup) test devices. The GenPrime DOA Reader System is for *in vitro* diagnostic use and is intended for prescription use in laboratories, point-of-care and workplaces by trained users. The test is not intended for over-the-counter use. The GenPrime DOA Reader System test devices cannot be read visually. The GenPrime DOA Reader and compatible DOA test devices qualitatively detect drug classes in human urine at the cutoff concentrations shown below:

OS Cup

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
BAR	Barbiturates (Secobarbital)	300 ng/mL
COC	Cocaine (Benzoylecgonine)	150 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

SK Cup

AMP	Amphetamine (d-Amphetamine)	500 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
MTD	Methadone	300 ng/mL
MOP 300	Morphine	300 ng/mL
MOP 2000	Morphine	2000 ng/mL
OXY	Oxycodone (Oxycodone)	100 ng/mL
PCP	Phencyclidine (Phencyclidine)	25 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

Configurations of the OS Cup and SK Cup may consist of any combination of the above listed drug analytes associated with the respective cup.

The GenPrime DOA reader system provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography / tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130082